Medicare Rx Update: May 9, 2006

Medicare Part D Claims Filing Window Extended to 180 Days...

Multiple payers, payer order issues, and retroactive eligibility have created challenges for coordinating benefits among Part D plans and other providers, especially during the initial start-up of Part D. As a result, CMS is requiring plans to implement 180-day claims filing timeframes for claims incurred during the period from January 1 through June 30, 2006. This timeframe is necessary to accommodate the identification and resolution of coordination of benefits issues requiring claims reversal and rebilling to appropriate payers. (See: 180-day.pdf)

To avoid having to reverse and rebill claims submitted through the Point of Sale Facilitated Enrollment (POS FE) process for dual eligible beneficiaries who are not actively covered by a PDP, CMS recommends that pharmacies pay special attention in following these POS FE guidelines. http://www.anthem.com/jsp/antiphona/apm/nav/ilink_pop_native.do?content_id=PWA082466

...and New Policy Guidance should minimize Incorrect Cost Sharing

Several factors have contributed to confusion surrounding cost sharing for full benefit dual eligible individuals. As a result, CMS has taken many steps to clarify and correct many beneficiaries' co-payment status.

- CMS has issued guidance asking Plans to reflect "Best Available Data," which includes accepting information from a nursing facility or advocate acting on behalf of the beneficiary. Furthermore, CMS has asked Plans to assure that critical data from the states are processed into their systems in a timely manner. (MemoIncorrectCopaysforDuals.pdf)
- CMS has encouraged Plans to work directly with pharmacies when implementing retroactive subsidy level changes. http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/QAReimbursingLTCPharmaciesDirectly_r04.18.06.pdf
- CMS has developed the following Q&A to clarify when an institutionalized dual eligible beneficiary qualifies for $0 co-payments (QAInstitutionalizedStatusandCopays.pdf).

What Formulary Changes can Plans make during the year?

Both industry best practices and the best interests of Medicare beneficiaries call for limited formulary changes during the benefit year. However, new opportunities for improving safety and quality in prescription drug use at a low cost will inevitably occur which may require formulary changes during the course of a plan year. Under Part D, no beneficiaries will be subject to a discontinuation or reduction in coverage of the drugs they are currently using, except for clear scientific and cost reasons including the availability of a new generic version of the drug or new FDA or clinical information. CMS' four-part formulary update (http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/MemoFormularyChangeGuidance_04.27.06.pdf) policy includes:

- Plans may expand coverage through lower co-payments or coinsurance, lower tiers, or deleting utilization management at any time during the year.
- Plans may only change their therapeutic categories and classes at the beginning of each plan year, except to account for new therapeutic uses and newly approved drugs.
- After March 1, Plans may make maintenance changes to their formulary (e.g., replacing brand name with generic drugs, making modifications based on new safety/effectiveness information). Those cases must be approved by CMS and Plans are required to notify CMS, SPAPs, prescribers, network pharmacies, pharmacists and "affected enrollees" 60 days before the effect of the change.

- Plans may only remove covered drugs, change to a less preferred tier or add utilization management requirements in accordance with CMS approval and proper notification to CMS, SPAPs, prescribers, network pharmacies, pharmacists and "affected enrollees." Plans may only make these changes if enrollees currently taking the affected drug are exempt from the change for the remainder of the plan year. CMS expects Plans to comply with this policy in 2007 and subsequent plan years.

  Note: Plans are not required to obtain CMS approval or provide 60 days notice when the FDA or a product manufacturer withdraws the drug from the market.

Increasing access to new Part D Vaccines...

Currently, most vaccines used by the Medicare population are covered under Medicare Part B. For the limited number of vaccines covered under Part D, enrollees receiving the vaccine in a physician's office have to pay the physician and then submit a paper claim to their part D plan for reimbursement. However, as new vaccines enter the market, Part D plans may need to consider additional approaches to ensure access to specific vaccines and to reduce beneficiary burden that can result from requiring initial payment out-of-pocket. This will be particularly important for dual eligibles with limited incomes. CMS is strongly encouraging plans to implement one or multiple approaches outlined in the attached guidance… and to pursue the implementation of any cost-effective, real-time billing option at the time of vaccine administration. (See: MemoVaccineAccess.pdf)

Part D Plan Level Enrollment data now available...

The Centers for Medicare & Medicaid Services (CMS) has posted additional plan level enrollment information to the Medicare Drug Coverage Enrollment Data web page. (http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/02_EnrollmentData.asp) The links include national and local enrollment data for PDPs and MA-PDs.

In Case You Missed it...A Recording of the Pharmacy Open Door Forum is online

Due to a high demand for a replay of the CMS Special Open Door Forum on the Pharmacy Quality Alliance, we have made a recording available at www.cms.hhs.gov/pharmacy.

Sign up for the PHARMACY_MMA-L list to receive the Medicare Rx Update at http://new.cms.hhs.gov/apps/mailinglists/

DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR BENEFICIARY CHOICES

MEMORANDUM

TO: All Part D Plan Sponsors

FROM: Abby L. Block, Director

RE: Claims Filing Timeframes

DATE: May 9, 2006

With the implementation of Medicare Part D, multiple payers, payer order issues, and retroactive eligibility have created challenges for coordinating benefits among Part D plans and other providers of prescription drug coverage— challenges that have been compounded by the systems and data difficulties that arose during the initial start-up of Part D. When all payer information is available at the point-of-sale, pharmacies typically serve as the intermediary facilitating coordination between Part D plans and other payers. During the initial implementation of Part D, pharmacies often lacked the information necessary to identify the correct primary payer for Part D drugs provided to Medicare beneficiaries enrolled in Part D plans. Consequently, through no fault of their own, pharmacies often billed the State and other payers instead of a beneficiary's Part D plan.

CMS has addressed a major portion of these situations through the State-to-Plan and Plan-to-Plan reconciliation processes. The balance, however, may require resolution through claims reversal and rebilling. In their role of facilitating coordination between Part D plans and payers, some pharmacies now are agreeing to reverse these incorrect claims and bill the proper Part D plan. We believe under these circumstances it would be inappropriate for Part D plans to impose the conventional 30-90 day timely filing limits rather than a less restrictive timeframe, as this industry standard generally applies only when the pharmacy is in a position to correctly bill, but fails to do so.

In April, we posted a Q&A on the CMS website concerning claims filing limits for receipt of rebilled claims, when such claims had been originally adjudicated by payers that were not responsible for primary coverage in accordance with the CMS guidelines on coordination of benefits. In recognition that the 30-90 day standard should not apply when effective coordination between payers was not possible due to the initial Part D implementation challenges, we called upon the industry to establish appropriate claims filing rules. However, we are hearing numerous complaints from pharmacies, States and other payers that some Part D plans have not done so, as we requested. As a result, we are exercising our authority to establish requirements to ensure effective coordination between Part D plans and SPAPs and other entities providing prescription drug coverage,

and will require plans to implement a 180-day claims filing timeframe for claims incurred during the period January 1 through June 30, 2006. This 180-day window is necessary to accommodate the identification and resolution of coordination of benefits issues requiring claims reversal and rebilling to appropriate payers.

Further guidance on coordination of benefits requirements in this area for 2007 will be issued for comment in the next several weeks.

If you have any questions about this issue, please contact your account manager. Thank you for your continued assistance with the implementation of the Part D benefit.

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CENTER FOR BENEFICIARY CHOICES

MEMORANDUM

TO: All Part D Plan Sponsors

FROM: Gary Bailey, Deputy Director

RE: Incorrect Cost Sharing Charges to Dual Eligible Beneficiaries

DATE: May 5, 2006

CMS has received numerous complaints concerning full benefit dual eligible beneficiaries being charged incorrect co-payments at the pharmacy. We are aware that a number of factors are contributing to the incorrect cost sharing for full benefit dual eligible individuals, including the lags associated with the scheduled reporting of information from the State to CMS, delays in Part D plans updating their systems, CMS's prior instruction to the States to report only current or prospective changes to beneficiary institutional status, and confusion in the long-term care provider community regarding when an institutionalized beneficiary qualifies for a zero copayment. To clarify this last point, an individual is considered institutionalized and qualified for a zero copayment when he or she is a full benefit dual eligible, a resident in a long-term care facility for a full calendar month, and under a covered Medicaid stay. Qualification for the zero copayment is effective on the first day of the month in which a beneficiary is expected to remain in a long term-facility for a full calendar month stay that is covered by Medicaid.

This memorandum is part of a three-step approach CMS is taking to address the issue of incorrect cost sharing. We initiated these efforts on March 22, 2006 by requesting that States begin to report retroactive changes in beneficiary institutional status on the State Monthly MMA Enrollment File no later than July 2006. As a second step, we are conducting additional outreach with the pharmacy community. In this outreach, we will explain when a beneficiary is considered institutionalized for the purposes of the zero copayment as well as address the data lag associated with monthly state reporting and its impact on the Part D plan's systems updates. We encourage you to undertake similar outreach efforts with your pharmacy networks.

The final step in this effort to mitigate incorrect cost sharing to dual eligible beneficiaries is to outline CMS's expectations in three areas related to Part D plans changing a beneficiary's cost sharing levels.

- Best Available Data -- Part D plans are required to use the "best available data" when they have knowledge that a beneficiary's cost sharing level is not correct. For example, if the plan has knowledge from the nursing facility, or an advocate acting on behalf of the beneficiary, that the individual is covered by Medicaid for his/her institutional stay or that the beneficiary is a full benefit dual eligible, the plan should make changes to its systems to accommodate the revised copayment level. As part of the confirmation process, plans will be required to keep appropriate records in order to reconcile low-income subsidy payments with CMS. We are working on an automated process for updating our systems when after a lag the correct copayment level is still not reflected.

- Plan Systems Lag -- Part D plans must update their systems for changes in copayment status when processing the transaction reply reports (TRRs) from CMS. We are aware of examples where institutional status indicators have been successfully transmitted by the states, but the drug claims are being processed against non-zero copayment amounts. Plans must ensure these critical systems updates are processed timely in order to avoid a prolonged lag period in which plan databases are not reflecting correct beneficiary copayment status.

- LTC Pharmacy Reimbursement for Incorrect Copayments Charged – Part D plans are encouraged to reimburse LTC pharmacies directly when implementing retroactive subsidy level changes. Plans should not automatically reimburse beneficiaries residing in long-term care facilities because it is unlikely that the LTC pharmacies have billed the beneficiaries for their copayments.

Please contact your account manager is you have any questions concerning this memorandum.

Part D Questions re:
Co-pays for Institutionalized Individuals
April 19, 2006

Question 1. We understand that LTC residents who are dual eligibles must reside in a LTC facility for one full calendar month before they qualify for the $0 co-pays. What happens when the resident is admitted to the nursing home, goes back into the hospital as an inpatient, and then is readmitted to the nursing home? Do the hospital stay and the readmission start the calendar month calculation over?

Response: The term "institutionalized" for the purpose of a Part D plan applying a zero co-pay refers to a full benefit dual eligible (an individual who has Medicare and full Medicaid benefits) who is an inpatient in a medical institution or nursing facility for which Medicaid made payment throughout a calendar month. Except for a first partial month of admission, it is generally not known whether or not the individual will be in the institution throughout the entire month, or whether Medicaid will pay throughout the month, until after the entire month has elapsed and the facility submits a claim to Medicaid. However, the co-pay determination must be made in real time at the point of sale, prior to complete information regarding institutionalization and Medicaid payment being known; therefore the following assumptions must be made in order to implement this policy.

In the first partial month of admission (i.e. when an individual is admitted on any day other than the first of the month, from a community setting to a medical institution for the remainder of the month) the individual is not considered institutionalized for part D purposes. Effective the first day of the following month, if the individual is expected to remain throughout the month, assume the co-pay should be at the institutional level of $0. Institutional status is not interrupted by transfers between medical facilities or by bed hold days. Institutional status is only interrupted by a discharge to a community setting such as the home or assisted living. Operationally, if the institutionalized individual remains Medicaid eligible, the individual's co-pay will remain at $0 throughout the remainder of calendar year 2006.

Question 2. During the interim period when a new nursing home admission -- who is dual eligible -- is waiting to meet their one calendar month requirement for $0 co-pays, is the facility ever responsible for paying the co-pays? Should the $1 & $3 co-pays be charged to the resident and deducted out of the Personal Needs Allowance (PNA) (as long as it meets State regulations) or paid for by private funds? If there is not enough money, no family, or the resident refuses to pay, can the LTC pharmacy ever charge the nursing home for the co-pays?

Response:

A Medicare skilled nursing facility (SNF) must ensure that residents obtain needed Part D drugs and may determine that it needs to pay Part D copayments in some instances to fulfill that obligation. Such costs are not separately billable to Medicare Part A or B but a SNF may charge the resident for these costs.

In a month in which co-pays are charged to the resident, these costs are the resident's liability. Under Medicaid, these costs are treated as a deduction from income when calculating the individual's contribution to the cost of institutional care, as are other medical and remedial services that remain the individual's responsibility. This deduction reduces the amount of income the resident is considered to have available to contribute toward the facility rate, and allows the resident to retain an amount necessary to satisfy the copayment liability. Because the available income to contribute toward the facility rate is less, the State payment under Medicaid to the facility will increase by the amount of the deduction. By contrast the PNA is a separate deduction for incidental or personal expenses, and is not for medical expenses such as co-pays. If the individual has insufficient income to cover the full cost of the co-pays in a given month, the difference may be carried over to the following month(s) until the liability is satisfied.

Under either Medicare or Medicaid, a long term care facility is not responsible for paying the pharmacy for a beneficiary obligation (e.g., copay, coinsurance, etc.) unless the facility has assumed this obligation by contract or such payment is required by state law.

It is important to make a distinction between payment of cost sharing and the delivery of drugs that are medically necessary. Under 42 CFR 483.60, a facility (either skilled nursing facility or nursing facility) must "provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in 483.75(h)." A facility may charge the resident for these costs.

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CENTER FOR BENEFICIARY CHOICES

May 8, 2006

Memorandum To: All Part D Sponsors

Subject: Increasing Part D Vaccine Access

From: Abby L. Block, Director, Center for Beneficiary Choices

As you know, Part D plans are required to provide access to vaccines not covered under Part B. During rulemaking, CMS described use of standard out-of-network requirements to ensure adequate access to the small number of inexpensive vaccines coverable under Part D, when the vaccines must be administered in a physician's office. The beneficiary would pay the physician and then submit a paper claim to their Part D plan for reimbursement up to the plan's allowable charge, possibly leaving a differential amount for which the beneficiary is solely responsible for paying. However, as newer vaccines come on the market with indications for use in the Medicare population, Part D vaccine in-network access will become more imperative.

With this in mind, we have been considering options to improve access to vaccines under the Drug Benefit without requiring up-front beneficiary payment. At this point, in advance of bid submissions, it is important that we outline additional approaches that we urge plans to implement when appropriate to improve access to vaccines. Plans are also strongly encouraged to develop additional approaches that minimize out-of-network coverage that requires out-of-pocket payment and the need for the beneficiary to submit paperwork for reimbursement.

In the attachment to this letter, we describe a range of in-network and facilitated out-of-network approaches that avoid forcing the beneficiary to pay the full cost of the vaccine at the time of the visit. Again, plans are not limited to these approaches and are encouraged to pursue the implementation of any cost-effective, real-time billing option at the time of vaccine administration. Additionally, plans may consider adopting several approaches depending upon the vaccine and its respective cost, storage requirements, and complexity of administration.

We would like to remind plans and providers that administration and professional fees may not be included as part of the Part D dispensing fee. Additionally, vaccine administration fees under Part B are only permitted for the administration of a Medicare-covered "preventative" vaccine – influenza, pneumococcal, Hepatitis B – along with "medically necessary" vaccines to treat illness or injury. Therefore, Part D plans may not separately pay for the administration of Part D vaccines in a physician's office.

We appreciate your continuing assistance with the implementation of Part D and look forward to your innovation in increasing vaccine access for our beneficiaries.

Attachment A. **Options to Ensure Adequate Access Under Part D to Covered Vaccines**

These are only four potential approaches to improve Part D vaccine access, and are not meant to limit plans in implementing a real-time billing process for vaccine reimbursement. In addition, these options are not meant to override the plans' obligations to provide out-of-network access when necessary.

Approach A: In Network Distribution Approaches

While we are in no way limiting plans to any specific approach, we do believe that an in-network, real time solution is the best method to increase vaccine access. In addition to the in-network options listed below, plans could reduce the burden of copay collection by establishing a benefit design with zero cost-sharing on vaccines.

1. In Network Specialty Pharmacy Distribution:

A Part D plan's specialty pharmacy could provide vaccines directly to physician offices. Under this scenario, the physician could call in a prescription, or the beneficiary could mail a prescription for the vaccine to the pharmacy. The pharmacy would fill the prescription for the vaccine, ship to the physician's office and bill the Part D plan for the vaccine. This model resembles the competitive acquisition program (CAP) being implemented by Medicare Part B in that the drug is shipped to the physician but the physician never purchases or gets reimbursed for the drug.

As a reminder Part D plans may not restrict access to Part D drugs by limiting distribution through a subset of network or specialty pharmacies, except when necessary to meet FDA limited distribution requirements or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy.

2. In Network Retail Pharmacy Access:

Enrollees could obtain a prescription from the physician and bring it to their local network retail pharmacy for filling. In some states it might be possible for the vaccine administration to be provided by the pharmacist. Forty-four states currently allow pharmacists to provide some type of vaccinations. Where it was safe to dispense these vaccines in the pharmacy, plans could explore utilization of their network pharmacists as a provider of adult Medicare Part D vaccines (Pediatric vaccines should continue to be provided by physicians).

Approach B. Out of Network Approaches: Facilitated Out-of-Network Access Approaches

Physicians cannot be network providers because they generally cannot meet the required contractual terms; rather, only pharmacies can meet them. While the following options are out-of-network arrangements between physicians and plans, we expect that these and similar options will reduce the need for up-front beneficiary payment by facilitating other forms of payment arrangements between physicians and plans, increasing access beyond the current regulatory out-of-network requirements,

and avoiding the incurrence of significant out-of-network costs by beneficiaries or CMS as part of the low-income subsidy.

1. Model Vaccine Notice for Physicians (Paper Claim Enhancement):

Part D plans would provide all enrollees with a vaccine-specific notice that the enrollees could bring to their physicians. This notice would provide information necessary for a physician to contact the enrollee's Part D plan to receive authorization of coverage for a particular vaccine, reimbursement rates, enrollee cost-sharing to be collected by the physician, and billing instructions. If the Part D plan authorizes payment, the physician would then bill the Part D plan using the physician standard claim form or ASC X12 electronic format (which Part D plans must accept) and would receive payment directly from the Part D plan.

Alternatively, physicians could access this information directly by calling the plans PA line.

2: Web-Assisted Electronic Physician Billing:

Using a commercially-developed web-based system based on the real-time NCPDP standard, physicians would electronically bill Part D plans for vaccines dispensed and administered in the physician's office. The physician would either enter into a contract with the Part D plan to be a non-pharmacy network provider, or alternatively, agree to accept Part D plan payment as payment in full payment as a condition of using the system.

In summary, we encourage plans to adopt any of these approaches as appropriate for the given vaccine and the beneficiary's circumstances. We also welcome additional exploration of other possible means to coordinate the billing of vaccines in the real-time environment of the Part D benefit with the current batch billing processes used by physicians.